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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,170	01/14/2005	Akihisa Takaichi	Q85324	9122

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,170	TAKAICHI ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment file on 6/16/2008 is acknowledged.

Claims 1, 3, 5-10 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set for–h in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi et al. (EP 0 443 047; hereinafter R1) in view of Bunger et al. (US 5,385,748; hereinafter R2), Takahata (US 4,212,893, hereinafter R3), and Chalupa et al. (US 5,597,604; hereinafter R4)

3. R1. discloses a liquid nutrient composition containing 3.5 to 7 g of total protein, 5 to 17 g of carbohydrate, and 1-5 g of fat in 100 ml of the liquid nutrient. The protein fraction is a protein hydrolysate having a molecular weight of 800-30,000. The carbohydrate fraction comprises one or more oligosaccharides consisting of maltotriose, maltotetrose, maltopentose and maltohexose. (Page 2, lines 42-46).

4. R1 teaches using various sources of proteins. R1 specifically discusses the enzymatically hydrolyzed proteins with a molecular weight in the range of 800 to 30,000 Daltons and more preferably 10,000 to 15000 Daltons. They teach using hydrolyzed gelatin (water soluble gelatin) and enzymatically hydrolyzed casein. These proteins are used in a proportion of 35 to 46 weight percent of the total protein. (Page 3, lines 7-17).

It is obvious to those of ordinary skill in the art to use protein hydrolysates of whey protein concentrate (WPC) or whey protein isolate (WPI) or desalted whey instead of casein hydrolysate at taught by R1. Using hydrolysates will prevent coagulation of proteins due to low pH of the beverage.

5. R1 teaches using carbohydrates which include mono-, di-, oligosaccharides, and polysaccharides including glucose, sucrose, maltohexose, starch and glycogen. (Page 3, lines 31-33).

6. The fat component of the nutrient fluid composition may include animal fat or vegetable fat such as rice oil, corn oil, soybean oil, butter, lard and other oils. (Page 3, lines 34-37).

7. R1 teaches of using colors, emulsifiers, stabilizers, preservatives and so on (Page 3, lines 47-48). It discloses a method for mixing and emulsifying the components in water (Page 2, lines 50-51). Formulation number 6 (Table 1, page 6) contains about 60% (w/w) water.

8. R1 is silent regarding the use of citric acid, ascorbic acid, agar, gellan gum, lactic acid, gluconic acid, phosphoric acid, locust bean gum, guar gum xanthan gum, and pH of the liquid composition.

9. R2 discloses a beverage thickener/emulsifier system. R2 teaches using guar gum from about 0.001 to 0.1% and preferably from 0.01 to 0.04%. (Col. 3, lines 33-41). The addition of guar gum will improve the mouthfeel.

10. R2 teaches using xanthan gum at 0.1 to 0.3% by weight of the total beverage components (Col. 3, lines 64- col. 4, line 7). Xanthan gum will stabilize the emulsion against separation.

11. R2 teaches using preservatives such as benzoic acid, butylated hydroxyanisole (BHA) etc. (Col. 6, lines 8-14). It also teaches using emulsifiers such as mono- and diglycerides, propylene glycol esters of fatty acids and lecithin (Col. 6, lines 17-23).

12. R2 discusses the pH of the beverage which can range from 3.0 to 6.0 and most preferably a pH from 3.0-4.5 (Col. 7, lines 20-28). They teach using acids such as citric, ascorbic, malic, tartaric, and phosphoric (Col. 8, lines 13-16). The acids are used as both acidulants and flavoring agents.

13. R1 and R2 are silent with respect to the use of agar and lactic acid in their beverage formulations.

14. R3 discloses an acidified whole milk emulsion beverage containing locust bean gum (emulsifier) in an amount of 0.1-1% by weight and an auxiliary stabilizing agent such as pectin or agar in an amount less than 0.1% by weight, agar being the preferred agent. (Col. 3, lines 14-26). R3 teaches using other organic acids such as gluconic acid and lactic acid and states that lactic and citric acid combination is preferred (col.2, lines 31-36).

15. The amount of citric acid being 1.5% in Example 1 (Col. 4).

16. R1, R2 and R3 are silent with respect to the use of gellan gum.

17. R4. discloses the use of gellan gum for making a gelled beverage. Their beverage contains 0.01% to 0.15% gellan gum. (Col. 1, lines 62-65). Gellan gum is used for stabilization and gelling purposes.

18. R4 teaches heating the mixture to between 140C and 212C while stirring to hydrate the gellan gum , filling the heated beverage composition in a beverage container and cooling the mixture (Col. 2, lines 10-15).

19. A liquid nutrient composition is disclosed by R1 in which the saccharide, fat and protein content of the beverage overlaps the ranges these components as presently claimed. R1 additionally discloses the use of protein hydrolysate in the beverage formulation. R2 teaches the stable pH range, citric acid content range and the use of gluconic and phosphoric acids as presently claimed. R3 discloses a range of the emulsifying agents overlapping the presently claimed range. It also teaches using agar as a gelling agent. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by adopting and using the teachings of R2, R3 and R4 to make a gelled beverage. One would have done so to benefit from a gelled beverage having nutritional as well as organoleptic qualities.. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making the gelled beverage of the instant application.

20. Claims 3 is rejected under 35 U.S.C. 103(b) as being unpatentable over R1 as applied to claim 1, further in view of Shimamura et al. (US 6,395,508; hereinafter R5).

21. R1 is silent with respect to the use of whey proteins in the nutrient liquid composition.

22. R5 discloses using whey protein concentrate (WPC) and whey protein isolate (WPI) to make whey hydrolyzates (Col. 8, lines 60-65) which may be used in sports beverages (Col. 3, line 25).

23. It would have been obvious to one of ordinary skill in the art, at the time the time the invention was made, to modify the teachings of R1 by adopting and using the teachings of R5 to make a beverage as presently claimed. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making such a beverage.

24. Claims 1, 3, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emoto (EP 1 046 347; hereinafter R6).

25. R6 discloses a beverage with pH of 3.3-4 comprising 50-90% water and 1-50% solids comprising 30-90% saccharide, 5-40% lipid, 2-60% protein including whey protein, 0.2-5% organic acids that include citric, ascorbic, tartaric, malic acid and gluconic acid wherein these acids are used in combination , 0.1-5% organic acid salt including sodium salt of citric acid,0.2-5% emulsifying agent and 0.2-5% gelling agent including pectin, agar, locust bean gum, xanthan gum and guar gum wherein the gelling agents are used in combination (Abstract and paragraphs 1, 9, 12-15, 17, 20, 23-24, 26-33).

26. Phosphoric acid is an acidulent known in the art and in carbonated beverages. It functions as a pH adjusting acid and also as a flavorant in carbonated beverages. Combination of acids in beverage formulations is taught by R6. Therefore, it is obvious to those of skill in the art to make use of a combination of acids including phosphoric acid.

27. R6. teaches mixing the ingredients, heating the mixture to emulsify them followed by cooling. (Paragraphs 39-42 and 47).

28. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R6 to formulate the gel beverage of the instant application. Absent any evidence to contrary and based on the teachings of the cited reference, there would have been a reasonable expectation of success in formulating a gel beverage.

Response to Arguments

Applicants' arguments have been thoroughly reviewed and considered.

1. Applicant argues on the quantity of agar as presently claimed and states that Takahata (R3) uses less 0.1% by weight while the amount claimed is 0.1-1% by weight.

a. R3 discloses the use of agar as a gelling agent. Therefore, the gelling concept by using agar is taught by R3. It is obvious to those in the art to monitor the amounts and optimize the agar content for the gelling function.

The only deficiency of Takahata (R3) is that R3 disclose the use of less than 0.1% agar, while the present claims require 0.1% or 0.2% agar.

It is apparent, however, that the instantly claimed amount of agar and that taught by R3 are so close to each other that the fact pattern is similar to the one in In re Woodruff , 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties".

In light of the case law cited above and given that there is only a "slight" difference between the amount of about agar disclosed by R3 and the amount disclosed in the present claims and further given the fact that no criticality is disclosed in the present invention with respect to the amount of agar, it therefore would have been obvious to one of ordinary skill in the art that the amount of agar disclosed in the present claims is but an obvious variant of the amounts disclosed in R3, and thereby one of ordinary skill in the art would have arrived at the claimed invention.

2. Applicants' argue that the use of citric, phosphoric and gluconic acid and the combination of these is not taught by the cited references.

a. R2 teaches of using citric and phosphoric acids and R3 teaches of using gluconic acid. Additionally R3 discloses the concept of combining acids. It is obvious to the skilled in the art that combination of acids can be used. It is also noted that phosphoric

acid can be used as a pH adjusting acid as well as an acidulent which affects the organoleptic quality of beverages.

3. Applicants' argue that the present invention provides unexpectedly superior results and that the gel beverage comprising the acid components shows high heat resistance.

a. Regarding the heat stability of the emulsion , R4 teaches of heating the mixture to between 140C-212C to hydrate the gum and cooling the mixture to form the gel in the containers. It is clear that such mixtures are heat stable and can be heated within the heating ranges necessary to make a gel beverage. It is also noted that the heat stability of proteins and protein hydrolysates depend on factors such as pH, presence of stabilizers, presence of fats, presence of emulsifiers and presence of salts. The references cited all teach certain aspects of this stability.

However, the data in this case is not persuasive for the following reasons. Applicants point to Tables 7 and 8 of the present specification which compares beverage within the scope of the present claims with beverage outside the scope of the present claims, i.e. comprising no gluconic acid or phosphoric acid. It is shown that the presently claimed beverage is superior in terms of heat resistance. However, the data is not persuasive given that there is only data at one value of each of the claimed ingredients and therefore the data is not commensurate in scope with the scope of the present claims. As set forth in MPEP 716.02(d), whether unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, "objective evidence of nonobviousness must be commensurate in scope with the claims which the

evidence is offered to support". In other words, the showing of unexpected results must be reviewed to see if the results occurred over the entire claim range, *In re Clements*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 980). Applicants have not provided data to show that the unexpected results do in fact occur over the entire range claimed range of acid components.

It is noted that there does not appear to be any disclosure of the pH of either the inventive beverage or the comparative beverage and therefore it is not clear if the pH is commensurate in scope with the scope of the present claims or if there is proper side-by-side comparison between the beverages with respect to pH.

The data is not persuasive given that the results depend on the temperature and at certain temperatures, there is no difference between the present invention and the comparative invention, i.e. at 75 C and 1-10 minutes both beverages rate A. Given that the present claims are not limited to any particular time and temperature, the data is not persuasive.

4. Applicants' argue that Emoto (R6) does not disclose, teach or suggest the use of a protein that does not coagulate at a pH of 3-4.

a. R6 discloses gelled foods and processes for producing such foods by employing gelling agents. It is true that that the emulsion produced by mixing lipids, saccharides, organic acids, emulsifying agents, gelling agents, and protein has an acidic pH equal to or close to the isoelectric point of the protein, however, a composite of an isoelectric gel of the protein and a gel formed with the gelling agents is obtained. Therefore, R6 is teaching and suggesting that a gelling agent may also be employed for the formation of

the beverage gel. As a result it is obvious to one of skill in the art, that if a protein that does not coagulate at low pH is employed, a gelling agent can be used to impose the gelling properties of the gel beverage. On the other hand, employing protein hydrolysates which do not coagulate at low pH is obvious to the skilled artisans. Further, attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in fact situation of the instant case. At page 234, the Court stated as follows:

This court has taken the position that new recipes for formulas for cooking food which involves the addition or elimination on common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, on one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant, by a proper showing, further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected and useful function. In re Benjamin D. White, 17 C.C.P.A. (Patents) 965, 39 F. 2d 974, 5 USPQ 267; In re Mason et al., 33 C.C.P.A. (Patents) 1144, 156 F. 2d 189, 70 USPQ 221.

5. Applicants argue that Takahata does not disclose the use of protein material that does not coagulate and is at least one material as now required in present claim 1.

a. Takahata teaches using gluconic acid which is one of the materials of claim 1. It is true that Takahata uses whole milk, but due to teachings they offer, the milk protein

does not coagulated at the pH range 2.5-4.5 which happens to be the range as presently claimed.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP 11-206351 A, WO 91/03948 A and JP 11-75726 A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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